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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,181	07/26/2001	Felix Theeuwes	DURE-023	9651

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EXAMINER	
LAM, ANN Y	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

Office Action Summary	Application No.	Applicant(s)	
	09/917,181	THEEUWES ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-22,25-27,29 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,26,27,29 and 30* is/are rejected.

7)☒ Claim(s) *25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-22, 26, 27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Valli, 4,437,856.

Valli discloses an elongate body (2) comprising a proximal end defining an inlet, and a distal end defining an outlet, the elongate body defining a passageway, see column 3, lines 25-27; and a diffuser element (11 or 16) operatively associated with the elongate body so as to define a diffusion space, wherein the diffusion space is in fluid communication with the elongate body passageway; wherein a drug at a first concentration is introduced into the elongate body inlet moves through the elongate body passageway, out the elongate body outlet, into the diffusion space, and substantially diffuses out through the diffuser element to exit the device such that the drug, upon deliver, is diluted to a second concentration that is less than the first concentration, see column 3, lines 25-35. As the fluid expands the membrane, while flowing out through holes 11', the concentration of the fluid as it exits the device is less than the concentration when the drug is introduced into the elongate body passageway. Alternatively, since the number of holes (11') is much greater than the number of holes

(12 on the elongate body, the concentration of the drug as it exits the device is less than the concentration of the drug as it is introduced into the elongate body.

As to claim 2, the diffuser element is the diffuser element comprising a material selected from the group consisting of a microporous membrane .

As to claim 3, the elongate body and the diffuser element are operatively associated by attachment to a drug delivery device, see Figure 2.

As to claim 4, the elongate body is defined by an exit orifice of a drug delivery device, see column 3, lines 25-35.

As to claim 5, the diffuser element is provided as a cap attached to a distal end of the drug delivery device, see Figure 2.

As to claim 6, the diffusion space is defined by an outer wall of the elongate body and an inner wall of the diffuser element, see column 3, lines 25-30.

As to claim 7, said diffuser element envelops at least a portion of said elongate body, see Figure 2.

As to claim 8, the diffuser element is microporous, see column 3, lines 11-14.

As to claim 9, the diffuser element is a dense membrane, see column 3, lines 11-14.

As to claim 10, the diffuser element is an ion-exchange membrane, see column 3, lines 11-14.

As to claim 11, said diffuser element distal end extends distally beyond the elongate body distal end, see Figure 2.

As to claim 12, the diffuser element distal is ring-shaped element, see Figure 2.

As to claim 13, the diffuser element is considered to be substantially impermeable to biological fluids or components of biological fluids.

As to claim 14, the diffuser element is selectively permeable to water, see column 3, lines 13-14.

As to claim 15, the device further comprises a diluter element (11) operatively associated with the elongate body so as to be in fluid communication with the elongate body passageway, the diluter element comprising a selectively water permeable material, see column 4, lines 41-45.

As to claim 16, the diluter element comprises at least a portion of a wall of the diffuser element, see column 4, lines 44-45.

As to claim 17, the elongate body comprises at least two outlets, see column 6, lines 2-3.

As to claim 18, the elongate body defines at least two passageways (9 and 10).

As to claims 19 and 24, the elongate body passageway is adapted for delivery of agent at a low volume rate, see column 3, lines 25-35.

As to claim 20, a drug delivery device is disclosed in column 3, lines 25-27.

As to claims 21 and 22, the drug delivery device is considered to be a convective drug delivery device, and is considered to be implantable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Valli, 4,437,856.

Valli discloses the invention substantially as claimed, except for the diffuser element having a Diffusion Coefficient value in the range between 4.1 x 10-6 and 3.3 x 10-5 ug/cm/sec. However, it would have been obvious to form the diffuser element as described above to have the specific Diffusion Coefficient as claimed, since it would have been obvious to form the diffuser element in a given size or to form the holes in a different size as necessary to accommodate a particular patient or particular medical procedure, see column 5, lines 56-61, and column 1, lines 6-7.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Valli, 4,437,856, in view of Burns et al. 5,221,260.

Valli discloses the invention substantially as claimed, see above, exceptfor the diffuser element comprising a polymer.

Burns et al. discloses a balloon catheter wherein the balloon comprises a polymer, see column 3, line 30. It would have been obvious to form the Valli balloon using a polymer, as taught by Burns et al., as a known material used to form balloons on balloon catheters.

Allowable Subject Matter

Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

A.L.
January 26, 2003